

## Information about Compilation of Safety Data Sheets

**Product:** PermaRed/AP-Auto  
**Manufacturer:** Diagnostic Biosystems, Inc.  
6616 Owens Drive, Pleasanton, CA 94588 USA  
**Article numbers:** K049, K049-110, K049-AUTO, K049-AUTO-110

All components of the aforementioned kit had been classified according to Regulation (EC) No. 1907/2006 (REACH) and to Regulation (EC) No. 1272/2008 (GHS/CLP).

For the kit component 2 (K049B), a Safety Data Sheet has been compiled (enclosure).

For the remaining kit component 1 (K049C), no Safety Data Sheet is required after classifications according to the Regulation (EC) No. 1907/2006 (REACH) and the Regulation (EC) No. 1272/2008 (GHS/CLP).

When handling the kit components, the general and specific safety precautions for laboratories and the corresponding directives have to be followed.

Date of issue: May 2023

**medac**

Product Safety  
Health, Safety & Environment (HSE)  
Phone: +49 4103 8006-0  
Fax: +49 4103 8006-100  
E-mail: [productsafety@medac.de](mailto:productsafety@medac.de)

Theaterstrasse 6  
22880 Wedel  
Germany

Attachment

**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 09.05.2023

Version number 1

Revision: 20.10.2020

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** PermaRed/AP, PermaRed/AP-Auto, PermaRed/AP-AutoPlus, Component 2**Article number:** K049B Comp2, K57B Comp2**Registration number**

The dangerous components are a mixture of several substances (see chapter 3). Registration numbers are not available for these substances as the substances or their use are exempted from registration according to Article 2 UK REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

**1.2 Relevant identified uses of the substance or mixture and uses advised against****Sector of Use** SU20 Health services**Product category** PC21 Laboratory chemicals**Process category** PROC15 Use as laboratory reagent**Application of the substance / the mixture**

Immunochemical reagent for detection / auxiliary reagent for in-vitro diagnosis.

**1.3 Details of the supplier of the safety data sheet****Manufacturer/Distributor:**

Manufacturer:

Diagnostic BioSystems

6616 Owens Drive

Pleasanton, CA 94588, USA

phone: +1 925 484-3350

Distributor:

medac GmbH

Theaterstrasse 6

22880 Wedel, Germany

phone: +49 4103 8006-0

**Informing department:**

Product Safety

productsafety@medac.de

**1.4 Emergency telephone number:**

Giftinformationszentrum-Nord, phone: +49 551 19 240 (service in German and English, 24 hours permanently accessible).

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labeled in accordance with Regulation (EC) No 1272/2008 (GHS/GB CLP).

**Hazard pictograms**

GHS07

**Signal word** Warning**Hazard-determining components of labelling:**

Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)

**Hazard statements**

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

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**Precautionary statements**

P273 Avoid release to the environment.  
 P280 Wear protective gloves / protective clothing / eye protection.  
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.

**2.3 Other hazards****Results of PBT and vPvB assessment****PBT:** Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.**vPvB:** Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

### SECTION 3: Composition/information on ingredients

**3.2 Mixtures****3.1. Chemical characterisation: substances** Not applicable. Product is a mixture.**Description:** Water based solution**Dangerous components:**

CAS: 55965-84-9 Index number: 613-167-00-5	Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)	≥0.0025-<0.025%
	<div> <div>☠</div> <div>Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330</div> </div> <div> <div>☠</div> <div>Skin Corr. 1C, H314; Eye Dam. 1, H318</div> </div> <div> <div>☠</div> <div>Aquatic Acute 1, H400 (M=100); Aquatic Chronic 1, H410 (M=100)</div> </div> <div> <div>☠</div> <div>Skin Sens. 1A, H317</div> </div>	
	Specific concentration limits: Skin Corr. 1C; H314: C ≥ 0.6 % Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 % Eye Dam. 1; H318: C ≥ 0.6 % Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1A; H317: C ≥ 0.0015 %	

**Additional information** For the wording of the listed H-phrases please refer to Section 16.

### SECTION 4: First aid measures

**4.1 Description of first aid measures****General information** First aider: Take care of self-protection.**After inhalation**

Supply fresh air.  
 Seek medical treatment in case of complaints.

**After skin contact**

Remove contaminated clothes.  
 Instantly wash with water and soap and rinse thoroughly.  
 In case of symptoms call a physician.

**After eye contact**

Rinse eyes cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

In case of onset of symptoms consult ophthalmologist.

**After swallowing**

Let rinse out mouth and then drink plenty of water.  
 In case of disorders consult doctor.

**Information for doctor**

Show Safety Data Sheet.  
 Treatment according to symptoms.

**4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.**Danger** No further relevant information available.**4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing agents** Product itself does not burn. Use fire fighting measures that suit the environment.**For safety reasons unsuitable extinguishing agents** For this mixture no limitations of extinguishing agents are given.**5.2 Special hazards arising from the substance or mixture**

In the event of fire formation of toxic gases possible.

In the event of fire may develop:

Carbon dioxide (CO<sub>2</sub>)

Carbon monoxide (CO)

**5.3 Advice for firefighters****Protective equipment:**

In case of fire of large quantities:

Stay in the danger area only with self-contained breathing apparatus.

Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

**Additional information**

Collect contaminated fire fighting water separately. It must not enter drains.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Advice for non-emergency personnel:

Do not inhale vapours/aerosols.

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

Advice for emergency responders: Protective equipment: see Section 8.

**6.2 Environmental precautions:** Do not empty into drains.**6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Afterwards clean with water and cleansing agent.

Dispose of the material collected according to respective national regulations.

Ensure adequate ventilation.

**6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Open and handle container with care.

Prevent contact with skin and eyes.

**Information about protection against explosions and fires:** No special measures required.**7.2 Conditions for safe storage, including any incompatibilities** No further relevant information available.**Storage****Requirements to be met by storerooms and containers:**

Store container tightly closed in cool, properly ventilated location.

Store at +2 °C to +8 °C.

**Information about storage in one common storage facility:** Not required.**Further information about storage conditions:**

Protect from heat and direct sunlight.

Protect from freezing.

The indications are valid for the whole package.

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Storage class See the respective national guidelines.

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7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

Components with critical values that require monitoring at the workplace:

DNELs Not applicable.

PNECs Not applicable.

Ingredients with biological limit values: Void.

CAS No. Designation of material % Type Value Unit

Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable.

Additional information: The official lists that were valid during the compilation were used as basis.

#### 8.2 Exposure controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See Section 7.

Appropriate engineering controls No further data; see Section 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Do not eat or drink while working.

Keep away from food and beverages.

Wash hands during breaks and at the end of the work.

Breathing equipment: Not required.

Hand protection Disposable medical gloves (AQL 1.5).

Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

The product quality has to comply with DIN EN 455.

Penetration time of glove material Not applicable.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Product has not been designed for permanent contact.

For the permanent contact gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

Eye/face protection Safety glasses (standard EN 166).

Body protection: Protective work clothing.

Environmental exposure controls Do not empty into drains.

Risk management measures Void.

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

General Information

Physical state

liquid

Colour:

Transparent

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<b>Smell:</b>	odourless
<b>Odour threshold:</b>	Not determined.
<b>Melting point/freezing point:</b>	ca. 0 °C
<b>Boiling point or initial boiling point and boiling range</b>	ca. 100 °C
<b>Flammability</b>	Not applicable.
<b>Lower and upper explosion limit</b>	
<b>Lower:</b>	Not applicable.
<b>Upper:</b>	Not applicable.
<b>Flash point:</b>	Not applicable.
<b>Auto-ignition temperature:</b>	Not applicable.
<b>Decomposition temperature:</b>	No information available.
<b>pH at 20 °C</b>	8.6
<b>Viscosity:</b>	
<b>Kinematic viscosity</b>	Not determined.
<b>dynamic:</b>	Not determined.
<b>Solubility</b>	
<b>Water:</b>	Fully miscible.
<b>Partition coefficient n-octanol/water (log value)</b>	Not applicable.
<b>Steam pressure at 20 °C:</b>	23 hPa
<b>Density and/or relative density</b>	
<b>Density at 20 °C</b>	1.00 g/cm <sup>3</sup>
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not determined.

## 9.2 Other information

<b>Appearance:</b>	
<b>Form:</b>	liquid
<b>Important information on protection of health and environment, and on safety.</b>	No further relevant information available.
<b>Self-inflammability:</b>	Not self-inflammable.
<b>Explosive properties:</b>	Not explosive.
<b>Solvent content:</b>	
<b>Organic solvents:</b>	< 0.6 %
<b>Water:</b>	98 %
<b>Solids content:</b>	< 2 %
<b>Change in condition</b>	
<b>Softening point/range</b>	
<b>Oxidising properties</b>	Not applicable.
<b>Evaporation rate</b>	Not determined.

## Information with regard to physical hazard classes

<b>Explosives</b>	Void
<b>Flammable gases</b>	Void
<b>Aerosols</b>	Void
<b>Oxidising gases</b>	Void
<b>Gases under pressure</b>	Void
<b>Flammable liquids</b>	Void
<b>Flammable solids</b>	Void
<b>Self-reactive substances and mixtures</b>	Void
<b>Pyrophoric liquids</b>	Void
<b>Pyrophoric solids</b>	Void
<b>Self-heating substances and mixtures</b>	Void
<b>Substances and mixtures, which emit flammable gases</b>	
<b>in contact with water</b>	Void
<b>Oxidising liquids</b>	Void
<b>Oxidising solids</b>	Void
<b>Organic peroxides</b>	Void
<b>Corrosive to metals</b>	Void

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**Desensitised explosives**

Void

**SECTION 10: Stability and reactivity****10.1 Reactivity** The mixture is chemically not reactive.**10.2 Chemical stability** The product is chemically stable under the indicated storage conditions.**Thermal decomposition / conditions to be avoided:**

No decomposition if used and stored according to the specifications.

**10.3 Possibility of hazardous reactions** No dangerous reactions known.**10.4 Conditions to avoid:** Heating.**10.5 Incompatible materials:**

Strong acids.

Strong bases.

Strong oxidising agents.

Metals.

Metallic compounds.

**10.6 Hazardous decomposition products:** No further relevant information available.**Additional information:** No further relevant information available.**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Data on the toxicity of this mixture are not available.

**Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC<sub>50</sub> values that are relevant for classification:** Quantitative data about toxicity of this product are not available.**Specific symptoms in biological assay:** No further relevant information available.**Skin corrosion/irritation** Slight irritations possible.**Serious eye damage/irritation** Slight irritations possible.**after swallowing:** Slight mucosal irritations in mouth, pharynx and oesophagus possible.**after inhalation:** Slight irritations possible.**Respiratory or skin sensitisation**

May cause an allergic skin reaction.

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.**Reproductive toxicity** Based on available data, the classification criteria are not met.**STOT-single exposure** Based on available data, the classification criteria are not met.**STOT-repeated exposure** Based on available data, the classification criteria are not met.**Aspiration hazard** Based on available data, the classification criteria are not met.**Other information (about experimental toxicology):** No further relevant information available.**Subacute to chronic toxicity:** No further relevant information available.**Additional toxicological information:** No further relevant information available.**Toxicokinetics, metabolism and distribution** No relevant information available.**Acute effects (acute toxicity, irritation and corrosivity)** No acute toxicity information available for this product.**Sensitisation** May cause sensitisation by skin contact.**Repeated dose toxicity** No further relevant information available.**11.2 Information on other hazards****Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information****12.1 Toxicity** No information available.

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**Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** No further relevant information available.**Other information:** No further relevant information available.**Behaviour in environmental systems:****Components:** Accumulation in organisms is not to be expected.**12.3 Bioaccumulative potential** Bioaccumulation is not to be expected.**12.4 Mobility in soil** No data available.**12.5 Results of PBT and vPvB assessment****PBT:** PBT assessment not available as chemical safety assessment not required/not conducted.**vPvB:** vPvB assessment not available as chemical safety assessment not required/not conducted.**12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.**12.7 Other adverse effects****Remark:** No further relevant information available.**Additional ecological information:****General notes:**

At present there are no ecotoxicological assessments.

Water hazard class 1 (Self-assessment): slightly hazardous for water.

### SECTION 13: Disposal considerations

**13.1 Waste treatment methods**

Product residues have to be disposed of according to the Waste Framework Directive as well as national and regional regulations in each the latest versions.

**Uncleaned packagings:****Recommendation:** Uncleaned packagings have to be disposed of in the same manner as the product residues.

### SECTION 14: Transport information

**14.1 UN number or ID number**

ADR, ADN, IMDG, IATA not regulated

**14.2 UN proper shipping name**

ADR	not regulated
	not regulated
ADN, IMDG, IATA	not regulated

**14.3 Transport hazard class(es)**

ADR, ADN, IMDG, IATA	
Class	not regulated

**14.4 Packing group**

ADR, IMDG, IATA not regulated

**14.5 Environmental hazards:****Marine pollutant:** No**14.6 Special precautions for user**

Not applicable.

**14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

**Transport/Additional information:**

Not classified as dangerous in the meaning of transport regulations as issued in the latest version.

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UN "Model Regulation": not regulated

### SECTION 15: Regulatory information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

**Labelling according to Regulation (EC) No 1272/2008** See Section 2.

**Hazard pictograms** See Section 2.

**Signal word** See Section 2.

**Hazard-determining components of labelling:** See Section 2.

**Hazard statements** See Section 2.

**Precautionary statements** See Section 2.

**Directive 2012/18/EU**

**Named dangerous substances - ANNEX I** hydrogen chloride

#### National regulations

#### Information about limitation of use:

Take note of the directive on the protection of young people at work in the latest version.

Take note of the directive on the safety and health at work for pregnant and breast feeding mothers and workers of childbearing age in the latest version.

**Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

**Other regulations, limitations and prohibitive regulations** Void.

**15.2 Chemical safety assessment:** A chemical safety assessment has not been carried out.

### SECTION 16: Other information

All information and recommendations are believed to be correct as of the date of this Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. medac GmbH shall not be held liable for any damage resulting from handling or from contact with the above product.

#### Relevant phrases

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

**Department issuing data specification sheet:** Product Safety

**Contact:** productsafety@medac.de

**Replaces version from:** 08.08.2017

#### Reason for alteration:

Update of the classification.

Adaption to directive (EC) No. 2020/878

#### Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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DNEL: Derived No-Effect Level (UK REACH)  
 PNEC: Predicted No-Effect Concentration (UK REACH)  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 Acute Tox. 3: Acute toxicity – Category 3  
 Acute Tox. 2: Acute toxicity – Category 2  
 Skin Corr. 1C: Skin corrosion/irritation – Category 1C  
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1  
 Skin Sens. 1: Skin sensitisation – Category 1  
 Skin Sens. 1A: Skin sensitisation – Category 1A  
 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1  
 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1  
 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

**\* Data compared to the previous version altered.**

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